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10/808,832	03/25/2004	Seiji Kondo	17558	6696

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EXAMINER	
PHONGSVIRAJATI, POONSIN	
ART UNIT	PAPER NUMBER
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,832	KONDO, SEIJI	
	Examiner	Art Unit	
	SIND PHONGSVIRAJATI	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Hommachi (JPO 2001-256305).

3. As to **Claim 1**, Hommachi teaches a distribution method of medical information, in which a single or a plurality of medical care/test institutions, an information management institution, and a single or a plurality of research institutions distribute the medical information with one another, the distribution method of the medical information (Hommachi, Abstract, Fig.1), comprising:

- a step of revising the medical information by removing private information from the medical information (Hommachi , paragraph 17);
- a step of transmitting the revised medical information obtained by use of apparatuses and/or consumables to obtain the revised medical information from a patient or a specimen to the information management institution from the medical care/test institution (Hommachi, paragraphs 21-22, the Examiner takes

the position it is inherent that the individuals [referred in item 17 from Fig.1] must sample their genome at a medical care/test institution);

- a step of searching a database by the use of the revised medical information received from the medical care/test institution to return a search result to the medical care/test institution, and changing the revised medical information received from the medical care/test institution into a predetermined format to store clinical data in the database in the information management institution (Hommachi, paragraph 21);
- a step of transmitting an inquiry for the clinical data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of searching the database based on the inquiry received from the research institution to return the search result to the research institution from the information management institution (Hommachi, paragraph 21), wherein the apparatuses and/or the consumables to obtain the changed medical information are supplied to the medical care/test institution from the information management institution at a charge or free of charge (Hommachi, paragraphs 34-36).

4. As to **Claim 2**, Hommachi teaches a distribution method of medical information, in which a single or a plurality of medical care/test institutions, an information management institution, a single or a plurality of research institutions, and a single or a plurality of manufacturing/selling institutions of apparatuses and/or consumables such

as a reagent associated consumable distribute the medical information with one another, the distribution method of the medical information (Hommachi, Abstract, Fig.1), comprising:

- a step of revising the medical information by removing private information from the medical information (Hommachi , paragraph 17);
- a step of transmitting the revised medical information obtained by use of apparatuses and/or consumables such to obtain the medical information from a patient or a specimen to the information management institution from the medical care/test institution (Hommachi, paragraphs 21-22, the Examiner takes the position it is inherent that the individuals [referred in item 17 from Fig.1] must sample their genome at a medical care/test institution);
- a step of searching a database by the use of the revised medical information received from the medical care/test institution to return a search result to the medical care/test institution, and changing the revised medical information received from the medical care/test institution into a predetermined format to store clinical data-in the database in-the information management institution (Hommachi, paragraph 21);
- a step of transmitting an inquiry for the clinical data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and

- a step of searching the database based on the inquiry received from the research institution to return the search result to the research institution from the information management institution (Hommachi, paragraph 21), wherein the apparatuses and/or the consumables to obtain the changed medical information are supplied to the medical care/test institution from the information management institution at a charge or free of charge (Hommachi, paragraphs 34-36), and
- a rebate is supplied to the manufacturing/selling institutions of the apparatuses and/or the consumables from the information management institution (Hommachi, paragraphs 33, and 37).

5. As to **Claim 3**, Hommachi teaches a distribution method of medical information, in which a single or a plurality of medical care/test institutions, an information management institution, and a single or a plurality of research institutions distribute the medical information with one another, the distribution method of the medical information (Hommachi, Abstract, Fig.1), comprising:

- A step of removing private information from a specimen;
- a step of sending the specimen with the private information removed to the information management institution from the medical care/test institution (Hommachi, paragraphs 21-22);
- a step of obtaining the medical information with respect to the sent specimen in the information management institution (Hommachi, paragraph 21);

- a step of searching a database by use of the medical information to return a search result to the medical care/test institution, and changing the obtained medical information into a predetermined format to store clinical data in the database (Hommachi, paragraphs 21-22);
- a step of transmitting an inquiry for the clinical data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of searching the database based on the inquiry received from the research institution to return the search result to the research institution from the information management institution (Hommachi, paragraph 21).

6. As to **Claim 4**, Hommachi teaches the distribution method of the medical information according to claim 1, further comprising:

- a step of transmitting specific medicine data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of updating the database by the received medicine data in the information management institution (Hommachi, paragraphs 16-21).

7. As to **Claim 5**, Hommachi teaches the distribution method of the medical information according to claim 2, further comprising:

- a step of transmitting specific medicine data to the information management institution from-the research institution (Hommachi, paragraphs 21 and 27); and
- a step of updating the database by the received medicine data in the information management institution (Hommachi, paragraphs 16-21).

8. As to **Claim 6**, Hommachi teaches the distribution method of the medical information according to claim 3, further comprising:

- a step of transmitting specific medicine data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of updating the database by the received medicine data in the information management institution (Hommachi, paragraphs 16-21).

9. As to **Claim 7**, Hommachi teaches the distribution method of the medical information according to claim 1, wherein a fixed global IP address is attached to the apparatus to obtain the medical information (Hommachi, paragraphs 25 and 35).

10. As to **Claim 8**, Hommachi teaches the distribution method of the medical information according to claim 2, wherein a fixed global IP address is attached to the apparatus to obtain the medical information (Hommachi, paragraphs 25 and 35).

11. As to **Claim 9**, Hommachi teaches the distribution method of the medical information according to claim 3, wherein a fixed global IP address is attached to the apparatus to obtain the medical information (Hommachi, paragraphs 25 and 35).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hommachi (JPO 2001-256305).

As to **Claims 10-12**, Hommachi does not specifically teach the distribution method of the revised medical information, further comprising: a step of subjecting the medical information to an interpolation preventive measure and encryption. But, the Examiner takes official notice that it would have been self-evident/inherent to encrypt an individual's data and clinical history to allow access to only authorize personnel in order to ensure a patient's privacy.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Hommachi to include preventive measures such as encryption, since in doing so would protect an individual's privacy and so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

14. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hommachi (JPO 2001-256305) in view of Layne et al. (US 5,841,975).

15. As to **Claims 13 and 14**, Hommachi does not specifically disclose the distribution method of the medical information, wherein the consumables are reagent associated consumables. Layne does disclose wherein the consumables are reagent associated consumables (col. 10 lines 52-60, col. 11 lines 55-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to have research reagent consumables within the teachings of Hommachi. One would be motivated to research reagent consumables to provide the research data to their clients, for example, drug companies (Hommachi, Abstract, paragraph 9).

Response to Arguments

16. Applicant's arguments filed 11/05/2008 have been fully considered but they are not persuasive.

Applicant has made the argument that Hommachi does not conceal private information regarding the medical information of the claimed invention. However, as one can plainly see in paragraph 17, Hommachi states, "When the personal information files (an address, a name, sex, age, family structure, etc.) are formed and search the gene information file from the network mentioned later, the personal information file is constituted so that it may not see." Therefore, the private information regarding the

medical information is removed and the concealment feature was anticipated by Hommachi.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SIND PHONGSVIRAJATI whose telephone number is (571) 270-5398. The examiner can normally be reached on Monday - Thursday 8:00am-5:00pm (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. P./
Examiner, Art Unit 3686
30 December 2008

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686